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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/907,263	07/17/2001	Alison M. Bendle	A-430F	7020

7590 12/31/2002

US Patent Operations/ TJG  
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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/907,263	BENDELE ET AL.
	Examiner	Art Unit
	Eileen B. O'Hara	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 10 September 2002.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 1 and 27-41 is/are pending in the application.

4a) Of the above claim(s) 34,35 and 38 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,27-33,36,37 and 39-41 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1 and 27-41 are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,10.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Claims 1 and 27-41 are pending in the instant application. Claims 42-71 have been canceled as requested by Applicant in Paper Number 11, filed Sept. 10, 2002.

***Election/Restrictions***

2. Applicant's election of Group I, and the species sTNF-RII, celecoxib and rheumatoid arthritis in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 34, 35 and 38 are withdrawn as being drawn to a non-elected invention, sTNFR-I.

Claims 1, 27-33, 36, 37 and 39-41 are currently under examination.

***Information Disclosure Statement***

3. The PTO-1449 filed August 30, 2002 (Paper No. 9) is present in the file. However, the references are not with the file and have not been found in the IDS storage facility. Therefore it is requested that Applicants submit a copy of the references for consideration with their response to this Office Action.

***Priority***

4. This application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent application 09/326,394. A statement reading "(now United States Patent No. 6,306,820)" should be included after "09/326,394, filed June 4, 1999" as the first sentence of the specification.

***Claim Rejections - 35 USC § 102***

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipate by Jacobs et al., US Patent No. 5,605,690, filing date Feb. 8, 1995.

Claim 1 encompasses a method for treating an acute or chronic inflammatory disease comprising administering to a patient a TNF binding protein and at least one other additional anti-inflammatory drug.

Jacobs et al. teaches that TNF antagonist proteins such as TNFR can be administered to patients in combination therapy with IL-1R and/or IL-2R to treat TNF-dependent inflammatory diseases, such as arthritis. Therefore, Jacobs et al. anticipates the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 27-33, 36, 37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al., US Patent No. 5,605,690, filing date Feb. 8, 1995, further in view of Feldman et al., US. Patent No. 5,633,145 (cited by Applicant), further in view of Anderson et al., J. Clinical Invest., Vo. 97., No. 11, pages 2672-2679, June 1996, and further in

view of Hubbard et al., *Arthritis & Rheumatism*, "SC-58635 (CELECOXIB), a novel COX-2 selective inhibitor, is effective as a treatment for osteoarthritis (OA) in a short-term pilot study". (1996) Vol. 39, No. 9 SUPPL., p S226.

Claims 1, 27-33, 36, 37 and 39-41 encompass a method for treating an acute or chronic inflammatory disease, wherein said inflammatory disease is rheumatoid arthritis, comprising administering to a patient a TNF binding protein and at least one other additional anti-inflammatory drug, wherein the drug is a COX2 inhibitor and may be celecoxib, and wherein the TNF binding protein has the amino acid sequence of SEQ ID NO: 4 (sTNF-RII) and may be glycosylated or non-glycosylated and is produced by recombinant methods.

The teachings of Jacobs et al. are summarized above. Jacobs et al. do not teach that the TNF binding protein may be the sTNF-RII and may be glycosylated or non-glycosylated and is produced by recombinant methods, wherein said inflammatory disease is rheumatoid arthritis, wherein the additional anti-inflammatory drug is a COX2 inhibitor and may be celecoxib.

Feldman et al. disclose the TNF binding protein sTNF-RII (SEQ ID NO: 25), that is 100% identical to SEQ ID NO: 4 of the instant application, teach that this protein is produced by recombinant methods, that protein can be glycosylated or non-glycosylated depending upon the host cell used (see column 5, lines 28-37), and the protein can be used to treat rheumatoid arthritis (see abstract).

Anderson et al. teach that COX-2 plays a prominent role in the inflammation associated with adjuvant arthritis and that COX-2 derived prostaglandins upregulate COX-2 and IL-6 expression at inflammatory sites.

Hubbard et al. teach that celecoxib, a COX-2 selective inhibitor, is effective as a treatment for osteoarthritis.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use a combination therapy for treatment of inflammatory diseases, such as rheumatoid arthritis, as taught by Jacobs et al., comprising administering a TNF binding protein (sTNF-RII protein as taught by Feldman et al.) and a COX-2 inhibitor (celecoxib as taught by Hubbard et al.), because both COX-2 and TNF play a prominent role in inflammation in arthritis. The skilled artisan would be motivated to do so because inhibiting two pathways involved in inflammation would be more effective than inhibiting just one pathway with a single drug, and such a combination therapy could also have synergistic effects. One of ordinary skill in the art would also know how to determine effective methods of administration. There would be a reasonable expectation of success, since methods of using combination therapy had been widely and successfully used in the field of medicine at the time the invention was made.

### ***Conclusion***

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR  
PRIMARY EXAMINER